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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,489	09/12/2003	Ursula Schindler	02481.1746-01	6324

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EXAMINER	
RAO, DEEPAK R	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/660,489	SCHINDLER ET AL.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *12-28* is/are allowed.

6)☒ Claim(s) *29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/856,069.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendment filed on January 27, 2006.

Claims 12-31 are pending in this application.

Withdrawn Rejections/Objections:

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

The following rejections are maintained:

Claims 29-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of hypertension, diastolic dysfunction, or erectile dysfunction, does not reasonably provide enablement for a method of activating soluble guanylate cyclase, generally; a method of treating all other disorders of claim 30 (i.e., cardiovascular disorders, thromboses, etc.). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The reasons provided in the previous office action are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'no reason to doubt the objective truth of the statements was provided'. The instant claims 29 and 31, however, are drawn to 'a method of activating soluble guanylate cyclase', without specifically identifying a disease state or condition and therefore

include any or all types of disease states that are associated with the recited mechanism. The instant claims appear to be in 'reach-through' claims. Reach through claims, in general have a format drawn to mechanistic, receptor binding or enzymatic functionality and thereby reach through any or all diseases, disorders or conditions, for which they lack written description and enabling disclosure in the specification. Further, there is nothing in the specification or the state of the art to provide how this particular enzymatic pathway correlates to the treatment of various diseases of the instant claims having diverse mechanisms involving various organs of the human body.

A detailed analysis of the *Wands* factors along with state of the references pertinent to the conditions recited in the instant claims was provided in the previous office action, which continues to be applicable to the pending claims. Applicant has not provided any asserting evidence the claimed compounds are effective activating soluble guanylate cyclase generally or effective in the treatment of the diverse disorders recited in the instant claims. As stated in the previous action, specification provides no evidence to show enablement for treating cardiovascular disorders, thromboses, etc. generally. Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied on are reasonably predictive of *in vivo* efficacy by those skilled in the art. See for example *In re Ruskin* 148 USPQ 221; *Ex parte Jovanovics* 211 USPQ 907. Applicant has not provided any reference(s) that forms sufficient evidence that claimed uses were art-recognized based on soluble guanylate cyclase activity relied on at the time of the effective filing date. MPEP 2164.05(a).

The specification only provides data for 18 of the exemplified compounds that can activate soluble guanylate cyclase. While such activity can warrant the treatment of hypertension, it does not have any correlation with cardiovascular disorders such as atherosclerosis; or thromboses, diabetes, liver cirrhosis; or improving learning capacity or memory power; etc. Many of the disorders have underlying factors that are not related to guanylate cyclase, or they have additional factors. For example, atherosclerosis is caused by plaques of cholesterol, lipids, and cellular debris built up in the inner layer of the artery wall, thus, the most effective treatment would be to reduce such plaque build up. Applicant has not provided how activating soluble guanylate cyclase would treat all types of cardiovascular disorders, including atherosclerosis, etc. Likewise, thrombosis is for example, related to Factor X of the blood coagulation pathway and not related to guanylate cyclase. Similarly, diabetes is related to the availability of insulin, or the production of glycogen while chronic renal insufficiency and liver cirrhosis have other factors such as alcohol consumption, hepatitis, and drug induced factor. Regarding improving learning capacity and memory power, there is nothing in the specification that would guide the skilled clinician to apply the claimed compounds for such as use.

Currently in the art, the drugs that treat hypertension, do not treat atherosclerosis while the cholesterol lowering agents that can reduce chances of atherosclerosis, are not administered for the treatment of hypertension. Likewise, none of the anti-diabetic agents can treat hypertension, atherosclerosis, thrombosis, etc. In other words, there is no single agent that can treat the many diseases of different etiologies. Therefore, to identify a subject in need of the activation of soluble guanylate cyclase activity or to treat the many diseases encompassed by the

instant claim using the large number of compounds of the instant genus, it would require undue experimentation since no single agent can treat the diseases encompassed in the instant claims.

Allowable Subject Matter

Claims 12-28 are allowed. The references of record, do not teach or fairly suggest the instantly claimed compounds.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deepak Rao
Primary Examiner
Art Unit 1624

April 16, 2006